

REMARKS/ARGUMENTS

Claim 6 has been rewritten into independent form by incorporating the subject matter of Claim 6 into previously non-elected Claim 1. Claim 1 now recites a milk product instead of a method for the production of a milk product and by adding an additional step of sterilizing and/or desiccating the milk product resulting from the bioconversion. Support for the sterilization and/or desiccating step is found on page 5, lines 4-6. Previously non-elected Claims 2-5 have also been amended to recite a milk product rather than a method for producing a milk product. As currently amended, Claims 1-5 are drawn to an immunostimulant milk product of elected Group II. Claim 6 has been canceled as being duplicative of currently amended Claim 1. Claim 7 has been amended to depend upon currently amended Claim 1. Claim 11 has been canceled.

Applicant has also added new Claim Numbers 12-15. Claim 12 recites a dehydrated immunostimulant milk food obtained from the milk product of Claim 1 and Claim 13 recites a sterilized immunostimulant milk food obtained from the milk product of Claim 1. Support for Claims 12 and 13 is found on page 5, lines 10-12. Claim 14 is directed to a method for increasing the resistance of a subject to infections by administering an immunostimulant milk product of Claim 1. Claim 15 recites the method of Claim 14, wherein the subject is an infant. Support for Claims 14 and 15 is found on page 5, lines 27-37.

I. Rejections under 35 USC §112, Second Paragraph

Claim 6-10 stand rejected under 35 USC §112, second paragraph as being incomplete for omitting essential elements because Claim 6 is dependent upon non-elected claim 1 and thereby fails to recite the details thereof. Independent Claim 1 has been amended to recite a milk product instead of a method for the production of a milk product and Claim 6 has been canceled. As currently amended, Claim 1 recites an immunostimulant milk product obtained by carrying out bioconversion on a milk substrate with the aid of a *Bifidobacterium* culture by keeping said substrate in contact with said culture, under conditions which are unfavorable to fermentation by *Bifidobacterium* and sterilizing and/or desiccating the milk product formed from the

bioconversion. Consequently, currently amended Claim 1 and any claims dependent thereon recite the details of the method for making an immunostimulant milk product.

II. Rejections under 35 USC §102(b)

Claim 6 is rejected under 35 U.S.C. §102(b) as being anticipated by Mutai et al. (US Patent No. 4,187,321) hereinafter "Mutai." Claim 6-9 are rejected under 35 U.S.C. §102(b) as being anticipated by Yang et al. (US Patent No. 5,711,977) hereinafter "Yang."

To establish anticipation, a prior art reference must disclose the invention as set forth in the claim. Specifically, a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference. Moreover, the identical invention must be shown in as complete detail as is contained in the claim. Applicant respectfully submits that both Mutai and Yang fail to teach each and every element of the currently claimed invention. Specifically, for reasons discussed below, neither reference teaches an immunostimulant food product without viable *Bifidobacterium*.

A. The Currently Claimed Invention

As currently claimed, independent Claim 1 recites a milk product obtained by first carrying out a bioconversion on a milk substrate with the aid of a *Bifidobacterium* culture by keeping the substrate in contact with the culture, under conditions which are unfavorable to fermentation by the culture and secondly sterilizing and/or desiccating the milk product formed in the bioconversion. The step of sterilizing and/or desiccating defines a product which no longer includes viable *bifidobacteria*. See page 5, lines 4-9 of the specification.

B. The Prior Art References

i) Mutai

Applicant respectfully submits that Mutai fails to teach each and every element of the currently claimed invention. Specifically, Mutai fails to teach an immunostimulant food product without viable *Bifidobacterium*. Additionally, Mutai does not teach a method of making an

immunostimulant food product resulting in the death of the *Bifidobacteria*. The Mutai reference teaches a method for producing foods containing at least two kinds of viable *bifidobacteria* by utilizing a mixed cultivation of oxygen-resistant mutant strains of *Bifidobacterium* with obligatory anaerobic *bifidobacteria*. According to the teachings of Mutai, industrial production of food containing *bifidobacteria* has not yet been made due to the difficulty in cultivation (column 1, lines 46-49). However, the inventors of Mutai successfully established a method for cultivating *Bifidobacterium* to provide food and drink containing it at a low price (column 1, lines 50-53). Accordingly, Mutai teaches the desirability of food products containing *bifidobacteria* and a method of manufacture thereof. Specifically, Mutai states:

When the mutant strains (dissociants) are cultivated with ordinary obligatory anaerobic bifidobacterai, the obligatory anaerobes grow satisfactorily in a pure cow's milk medium under aerobic conditions.

See column 1, line 66 through column 2, line 1.

Mutai provides food and drink products containing more than one species of *Bifidobacterium* such that it provides products collectively excellent in physiological activity and taste is achieved (column 2, lines 11-25). Clearly, all food products disclosed by Mutai necessarily contain viable *bifidobacteria*. Unlike Mutai, the products manufactured according to the methods of the currently claimed invention do not include viable *bifidobacteria* as a result of the sterilizing and/or desiccating step. Consequently, Mutai fails to anticipate independent Claim 1 or any claims dependent thereon.

ii) Yang

Applicant also respectfully submits that Yang does not teach each and every element of the present invention. Similar to Mutai, Yang fails to teach an immunostimulant food product without viable *bifidobacteria* or a method of making such food products resulting in the death of the *bifidobacteria*. In general, Yang is directed to *bifidobacteria* strains having tolerance in gastrointestinal environments and methods for culturing the same. Additionally, Yang teaches that these strains can be added to a variety of food products and in an amount "such as to yield a

bacteria count of $10^6 - 10^9$ cfu per gram or milliliter." See column 6, lines 20-38. Yang also teaches that "the gastric acid-tolerant strains isolated by the invention can pass [through the] stomach against gastric acid with increased survivability." See column 6, lines 50-52. Furthermore, Yang teaches that the resistances against gastric acid and bile salt satisfy the requirement of reaching effectively into the intestine after oral administration to assure that the function of the product can be promoted (column 6, lines 61-64). Clearly, all food products disclosed by Yang necessarily contain viable *bifidobacteria*. Accordingly, Yang fails to teach an immunostimulant food product which does not contain viable *bifidobacteria* or a process of making a food product including a sterilization and/or dessicating step resulting in the death of *bifidobacteria*. Consequently, Yang fails to anticipate independent Claim 1 or any claims dependent thereon.

II. Rejections under 35 USC §103(a)

Claims 6-10 rejected under 35 U.S.C. §103(a) as being unpatentable over Yang. As currently claimed, independent Claim 6 recites a milk food product obtained by first forming a milk product by carrying out a bioconversion on a milk substrate with the aid of a *Bifidobacterium* culture by keeping the substrate in contact with the culture, under conditions which are unfavorable to fermentation by the culture and secondly sterilizing and/or desiccating the milk product formed in the bioconversion.

To establish a prima facie case of obviousness there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference. Additionally, the cited reference must teach or suggest each and every claim limitation. Furthermore, the teaching or suggestion must be found in the prior art, not in applicant's disclosure.

It is respectfully submitted that the cited reference fails to teach or suggest every element of the currently claimed invention. As discussed in detail above, Yang fails to teach or suggest an immunostimulant food product without viable *bifidobacteria* or a method of making such food products resulting in the death of the *bifidobacteria*. Since the invention set forth in Yang is directed towards providing *bifidobacteria* strains for food products such that the strains

survive against gastric acid after oral consumption, Yang clearly does not suggest a food product without viable *bifidobacteria*. Accordingly, the Examiner has not established a *prima facie* case of obviousness because the reference cited does not teach or suggest each and every claimed limitation. Since the cited reference fails to teach or suggest each and every element of the currently claimed invention, the 35 USC §103(a) rejections have been overcome.

Additionally, the Examiner has not provided any support that the prior art reference, or the knowledge generally available to one of ordinary skill in the art, provides any suggestion or motivation to modify the food products containing gastric acid and bile salt resistant *bifidobacteria* strains of Yang to kill these resistant *bifidobacteria* strains to form an immunostimulant food product without viable *bifidobacteria* strains. Furthermore, the mere fact that the prior art could be so modified would not make the modification obvious unless the prior art suggested the desirability of the modification. Consequently, there necessary suggestion or motivation for modifying the cited reference is not present. Accordingly, Examiner has failed to establish a *prima facie* case of obviousness and the rejections under 35 USC §103(a) have been overcome. Therefore, Claim 1 and all Claims dependent thereon are non-obvious in view of the prior art cited.

For these and the other reasons stated above, it is respectfully submitted that the rejections under 35 U.S.C. §102(b) and §103 (a) have been overcome and that all Claims are patentable over the cited references.

III. Conclusion

In view of the remarks made above, Applicant submits that the pending Claims are in condition for allowance. Applicant respectfully requests that the claims be allowed to issue. If the Examiner wishes to discuss the application or the comments herein, the Examiner is urged to contact the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required

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therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "John E. Johnson, III". The signature is fluid and cursive, with a long horizontal stroke at the end.

John E. Johnson, III
Registration No. 58,367

Customer No. 00826
ALSTON & BIRD LLP
Bank of America Plaza
101 South Tryon Street, Suite 4000
Charlotte, NC 28280-4000
Tel Charlotte Office (704) 444-1000
Fax Charlotte Office (704) 444-1111

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